REMARKS

This is in response to the Final Office Action of May 11, 2007. Claims 1-12 are currently pending in the present application, wherein claim 1 is the only independent claim. Claim 13 is new.

In the Office Action, the Examiner (1) rejected claims 1-5 and 8-11 under 35 U.S.C. 102 (b) as being anticipated by Elson et al. (US 4,643,389); (2) rejected claims 1-5 and 8-12 under 35 U.S.C. 103 as being unpatentable over Utterberg (US 6,089,527) in view of Elson; (3) rejected claim 6 under 35 U.S.C. 103 as being unpatentable over Elson in view of Baumdicker et al. (US 6,298,526) and; (4) rejected claim 7 under 35 U.S.C. 103 as being unpatentable over Elson in view of Stephens (US 4,193,174). For the reasons set forth below, Applicants respectfully submit that the pending claims are neither anticipated nor would they have been obvious in view of the cited art.

Claims 1-5 and 8-11 Are Not Anticipated by Elson et al. (US 4,643,389)

First, Applicants turn to the rejection of claims 1-5 and 8-11 under 35 U.S.C. 102 (b) as being anticipated by Elson. Applicants respectfully submit that independent claim 1 and the respective dependent claims are not anticipated by Elson.

Specifically, claim 1 is directed to a flow control clamp comprising a flexible body having a first leg and a second leg disposed in a general facing relationship when in a first spaced apart position and in a second closed position, the legs being movable from the first position to the second position. Claim 1 further recites a pair of apertures in the body for receiving a flexible tube therethrough. Finally, Claim 1 recites at least one tube contacting member carried by one of the legs for clamping a tube when the legs are in the closed position. The first and second legs are adapted to irreversibly secure the

legs together in the second closed position.

Applicants respectfully submit that the flow control clamp of claim 1 is neither shown nor suggested in the Elson patent. Specifically, Elson does not disclose first and second legs including surfaces disposed to irreversibly secure the legs together in a second closed position. As described in further detail in the specification of the present application, "irreversibly" closed or closable means that the flow control clamp, once in the closed position, is not readily releasable from the closed position in the normal and intended mode of operation. An "irreversibly" closed or closable flow control clamp can only be released from the closed and locked position by extraordinary and unintended manipulation of the clamp, including breakage of the clamp. See, for example, specification pages 5-6.

In contrast, Elson teaches that body members (arms) 25, 27 can be moved from a clamping position to a releasing position in which the arms 25 and 27 are movable away from each other. See co. 1 lines 32-33 and 60-65. Elson further describes that the arms 25 and 27 are relatively movable away from each other to a releasing position in which the clamping members 47 impose essentially no restriction to flow through the tube 19. The hinges 29 and the wall portion 31 are resilient, and resiliently oppose movement of the arms to the clamping position. See Elson col. 3, lines 48-57.

The Examiner has suggested that Elson describes a "positive lock" that holds the clamp shut, and therefore, the clamp of Elson is irreversible. However, Applicants respectfully submit that the Examiner has misconstrued the description in Elson to mean that the clamp of Elson is "irreversible" as presently claimed when in fact, it is reversible. Specifically, Elson describes that web 45 and tab 49 serve to hold the two arms (25, 27) and the two side walls (23, 31) in a "loop" or generally rectangular

configuration. However, the "positive lock" is in no way analogous to the recited "second closed position" of claim 1 as within this "loop" configuration (practiced by the so-called "positive lock"), the arms 25 and 27 remain movable between a clamping position (in which the clamping members 47 tightly compress the tube 19 to block flow of fluid therethrough) and a releasing position (in which fluid can flow through tube 19, as seen in Figure 2). See col. 4, lines 10-31. Thus, it is clear that the arms in Elson are moveable between the open and closed positions even when web 45 and tab 49 are engaged, and, once in the closed position, the clamp can be reopened without extraordinary and unintended manipulation of the clamp, including breakage of the clamp to allow fluid to flow through tube 19. See Elson, col. 4, lines 42-45. Thus, the arms of the Elson device are not irreversibly secure as required by claim 1.

For at least these reasons, Applicants respectfully submit that independent claim 1 and the respective dependent claims are not anticipated by the Elson patent.

Claims 1-5 and 8-12 Would Not Have Been Obvious Over Utterberg (US 6,089,527) in view of Elson

Next, Applicants turn to the rejection of claims 1-5 and 8-12 under 35 U.S.C. 103 as being unpatentable over Utterberg (US 6,089,527) in view of Elson, and submit that independent claim 1 and the respective dependent claims would not have been obvious over Utterberg either alone or in combination with Elson. Specifically, Utterberg does not describe first and second legs including surfaces disposed to irreversibly secure the legs together in a closed position. Instead, Utterberg discloses a squeeze clamp for tubing, which is reversible between an open and closed position, and the Examiner has expressly acknowledged this fact – that is, the Examiner indicated that "Utterberg does not disclose that the first and second surfaces are adapted to irreversibly secure the

legs together in a closed position."

The Examiner suggested that it would have been obvious to combine the clamp of Elson with the clamp of Utterberg to achieve the claimed subject matter. However, it is respectfully submitted that even if one were to combine the reversible clamp described by Utterberg with the clamp of Elson, the resulting device would still not have the features of the claimed irreversible flow control clamp. Specifically, as described in detail above, Elson does not describe a clamp that is irreversibly closable as presently claimed, and actually teaches away from such a configuration. Applicants note that that the illustrated embodiments and figures of Elson clearly show a clamp that can be repeatedly moveable between open and closed positions depending on the specific medical procedure being carried out. See, for example, col. 4, lines 42-44 of Elson. Therefore, it cannot be properly concluded that the clamp described in Elson is irreversible as required by independent claim 1. Thus, claim 1 and the respective dependent claims would not have been obvious over Utterberg either alone or in combination with Elson.

Claims 6 and 7 Would Not Have Been Obvious Over the Cited References

Next, Applicants turn to the rejection of dependent claims 6 and 7 over Elson in view of the '526 patent to Baumdicker and the '174 patent to Stephens, respectively.

In this regard, Applicants note that Claims 6 and 7 are dependent on claim 1. Applicants submit that, for at least the reasons stated above that claim 1 is patentable over Elson, which are incorporated herein by reference, claims 6 and 7 also would not have been obvious over Elson either alone or in combination with Baumdicker and/or Stephens.

New Claim 13

By this amendment, Applicants have added new claim 13. Claim 13 recites a flow control clamp and tube comprising a flexible body having a first portion and a second portion wherein the first portion and second portion are movable from a first open position to a second closed position. Claim 13 further recites a flexible tube extending between the first and second portions and at least one tube contacting member carried by one of the portions for compressing the tube when the portions are in the closed position such that fluid flow through the tube is substantially prevented. The first and second portions are adapted to irreversibly maintain the closed position.

Support for the subject matter of claim 13 can be found in the specification of the present published application on page 1, para. [0011] through page 2, para. [0012] and page 3, para. [0036]. Also see, for example, Figures 7 and 8.

For the same reasons discussed above with respect to independent claim 1, which are incorporated by reference herein, new claim 13 is also not anticipated and would not have been obvious over the cited references. In particular, like claim 1, claim 13 recites that the first and second portions of the flow control clamp are movable from a first open position to a second closed position and the first and second portions are adapted to irreversibly maintain the closed position. Claim 13 specifically defines the second "closed" position as one in which fluid flow through the tube is substantially prevented. None of the cited references describe a flow control clamp in which first and second portions are adapted to irreversibly secure the portions together in a closed position to substantially prevent fluid flow through the tube.

For example, it can be seen in Figure 2 of Elson that fluid can flow through the tube when the clamp is in the "unclamped" (yet closed-loop) position. The clamp of Elson is then moveable to a closed position, as seen in Figure 4, and then moveable back to an unclamped position, in which fluid flow through the tube can resume. See, for example, col. 1. lines 58-63 and col. 4. lines 32-52. Thus, the clamp of Elson does not describe first and second portions adapted to irreversibly maintain the closed position as required by claim 13.

Finally, Applicants are submitting an Information Disclosure Statement citing additional references that have recently come to Applicants' attention. Applicants request that these references be considered and made of record. A Request for Continued Examination accompanies this Amendment and Information Disclosure Statement.

CONCLUSION

For the reasons described above, Applicants respectfully submit that claims1-13 are novel and would not have been anticipated or obvious in view of the cited art. Applicants respectfully request that the claims be reconsidered and allowed.

Respectfully submitted,

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